

Remarks

Applicants Interview Summary

Initially, Applicants thank Examiner Santos and Examiner Smith for the courteous telephonic interview extended to Robert Enyard on August 18, 2009. During the interview, Applicants' representative, Robert Enyard Jr., described differences between the claims of the present application and the Grimson reference (U.S. Patent No. 5,999,840). For example, Applicants explained the difference between the operation site measurement techniques described in Grimson and the techniques described in Applicants present application. In particular, applicants pointed that Grimson patents describes techniques for measuring the surface of the skin before and during surgery, whereas applicants described measuring the surface of the skin during surgery and further measuring the unexposed portion of the operation site.

Examiner Smith acknowledged that Grimson does not teach measuring below the surface, but requested clarification regarding the meaning of the term "unexposed." Applicants' representative explained that an unexposed portion is below or beneath the surface and identified several portion of the specification that support this meaning. For example, Applicants representative cited the following.

"At step 138, based on data of the plurality of ultrasonic tomographic images fetched in from the ultrasonic tomographic device 34, feature points (including points corresponding to feature portions of a brain, such as brain grooves, arteries, veins and so on, and also including points corresponding the boundaries between a brain tumor and a healthy portion), which feature points are located *within* the brain (an unexposed portion in which the three-dimensional coordinates can be detected by the three-dimensional shape measurement device 30) and are readily recognized on an image, are respectively extracted from each of ultrasonic tomographic images." (See Application, paragraph 69.)

Applicants pointed out that the cited section refers to an example operation on a brain in which feature points located *within the brain* are detected. The terms *within the brain* are described in the same sentence as an unexposed portion in which the three-dimensional coordinates can be detected. Examiner Smith agreed that the cited portion provides clarification regarding the meaning of unexposed, but suggested adding or changing the claim

language to include “below the surface” or some equivalent. As explained below, Applicants have amended the claims as suggested to further clarify the meaning of “unexposed.”

Examiner Smith also indicated that several of the claims were not in proper means plus function format and suggested amending the claims to the appropriate format. Applicants have amended the appropriate claims as suggested.

Status of the Claims

Claims 1-11 are presently pending. Claims 1, 9, 10, and 11 have been amended. Applicants aver that no new matter has been added by this amendment.

Claim Rejections Under 35 U.S.C. § 112

Claim 11 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. In particular, the Examiner asserts that “It is not clear what the applicant is claiming. For example, is the applicant claiming the function of the code or the code itself?” (See Office action at page 2.) Applicants submit that amended claim 11 is in compliance with 35 U.S.C. § 112, second paragraph, and request that the rejection of claim 11 be removed.

Claim Rejections Under 35 U.S.C. § 101

Claim 11 stands rejected under 35 U.S.C. § 101 as being directed to non-statutory subject matter. In particular, the Examiner asserted that claim 11 is not tied to a particular machine or apparatus nor does it transform a particular article into a different state or machine or thing, thereby failing the machine or transformation test. (See Office action at page 3.) Claim 11 has been amended and defines the necessary structural and interrelationships between the claimed systems.

Amended claim 11 defines structural and functional interrelationships between a scanning device, a probe, and a computer, which permit the surgical operation supporting program’s functionality to be realized. Claim 11 recites structural components and, thus, constitutes a machine or a manufacture within the meaning of 35 U.S.C. § 101. Accordingly, Applicants submit that amended claim 11 is directed to statutory subject matter and in compliance with 35 U.S.C. § 101.

Claim Rejections Under 35 U.S.C. § 102

The Examiner also rejected pending claims 1, 4, 6, 7, and 10 as being anticipated by U.S. Patent No. 5,999,840 to Grimson et al. (“Grimson”). The rejection is respectfully traversed.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” (citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).). A claim cannot be rejected under 35 U.S.C. § 102 unless each and every claim limitation is found in the cited reference. Moreover, unless a reference discloses within the four corners of the document not only all of the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the claim, it cannot be said to prove prior invention of the thing claimed and, thus, cannot anticipate under 35 U.S.C. § 102. *Net MoneyIn, Inc. v. Verisign, Inc.* 545 F.3d 1359 (Fed Cir. 2008).

The present application relates to a surgical operation supporting apparatus that utilizes surface configuration data obtained by optically measuring the surface of a brain using the three-dimensional shape measurement device during surgery, carrying out image pickup of the surface of the brain using the video camera during surgery, and measuring unexposed area data, where the unexposed area includes portions below the surface of the operation site, with ultrasonic waves by means of the ultrasonic tomographic imaging device. In addition, an MRI image is collected and corrected, with the corrected MRI image representing the current state of the brain with a high degree of precision that is displayed during the surgical operation. Therefore, it is possible for the surgeon to observe the current state of the brain including the displacement or distortion that occurs during the surgical operation.

Grimson discloses a system for registration of three-dimensional data sets including a first data set of 3D tomographic images obtained before the operation, a second data set of 3D surface configuration data of the surgery environment, and a third data set of 3D images of the surgical instrument. The system of Grimson registers the above data sets on the same three-dimensional coordinates and superimposes the images upon on another.

Regarding amended claim 1, Applicants submit that Grimson fails to disclose each and every element as set forth in amended claim 1, and therefore also fails to teach the same arrangement or combination of elements in the same way as recited in amended claim 1.

Grimson fails to disclose, teach, or suggest a second acquisition means for measuring an unexposed portion of the operation site with ultrasonic waves during surgery, “the unexposed portion of the operation site being below the surface of the operation site.” Grimson does not teach, disclose, or suggest correcting the three-dimensional tomographic images obtained before the operation by measuring the unexposed portion that displaces and deforms during the operation. In particular, Grimson does not teach, disclose, or suggest “acquiring second position information representing a three-dimensional position of each of points in the unexposed portion of the operation site” and “based on the first position information acquired by said first acquisition means and the second position information acquired by said second acquisition means, estimates estimating displacement and distortion at each of the points in the operation site using a three-dimensional model generated based on a plurality of high-definition tomographic images of the operation site.”

For the reasons discussed above, Applicants submit that Grimson not only fails to teach, or suggest each and every element of claim 1, but the cited references clearly do not disclose all of the limitations arranged or combined in the same way as recited in claim 5. Thus, independent claim 1 is not anticipated by the Grimson reference.

Support for the amendments to independent claim 1 can be found in the present application. For example, “At step 138, based on data of the plurality of ultrasonic tomographic images fetched in from the ultrasonic tomographic device 34, feature points (including points corresponding to feature portions of a brain, such as brain grooves, arteries, veins and so on, and also including points corresponding the boundaries between a brain tumor and a healthy portion), which feature points are located within the brain (an unexposed portion in which the three-dimensional coordinates can be detected by the three-dimensional shape measurement device 30) and are readily recognized on an image, are respectively extracted from each of ultrasonic tomographic images.” (See Application at paragraph 69). Furthermore, “Due to the three-dimensional coordinates of the node point which is determined as that corresponds to any of the points on the brain surface represented by the surface measurement data being replaced by three-dimensional coordinates of the corresponding point (the three-dimensional coordinates in the MRI coordinate system represented by the surface measurement data), and also due to the three-dimensional coordinates of the node point which is determined as that corresponds to any of the feature

points within the brain represented by the unexposed area data being replaced by the three-dimensional coordinates of the corresponding feature point (the three-dimensional coordinates in the MRI coordinate system represented by the unexposed area data), as is also shown in FIG. 6B for instance, the position of the node point corresponding to any one of the points on the brain surface represented by the surface measurement data or any one of the feature points within the brain represented by the unexposed area data is corrected, from among the node points constituting the three-dimensional brain model.” (See Application at paragraph 73). The above examples are not meant to be limiting and other examples exist.

The remarks made above with respect to independent claim 1 and the Grimson patent similarly apply to independent claim 10. With respect to amended independent claim 10, Grimson fails to disclose, teach, or suggest “an unexposed portion of the operation site is measured with ultrasonic waves during surgery, so as to acquire second position information that represents a three-dimensional position of each of points of the unexposed portion in the operation site, the unexposed portion of the operation site being below the surface of the operation site.”

The Examiner asserts that the “second position information” of the present invention is disclosed in Grimson as 3D tomographic images. However, when comparing the present application and Grimson, it can be found that the images obtained from elements 106 and 116 of Grimson correspond to the “first position information” of the present application. Likewise the 3D tomographic images of Grimson correspond to the “high-definition tomographic images” of the present application. Therefore, it can be determined that Grimson does not disclose the “second position information representing a three-dimensional position of each of points in **the unexposed portion of the operation site**” as recited in claims 1, 10, and 11 of the present application.

Grimson discloses that “The laser scanning unit 106 used could be substituted for by any of a number of surface 3D scanners. There are numerous other conventional methods, including laser radar and more fringe analysis that could be used in the system 100. Other non-contact sensor types, including ultrasound or radar, are possible, as are a wide array of contact (probing) types of measurement devices. All that is required is the derivation of a modest number of accurate skin surface 3D points.” (See Grimson, column 5, lines 29-37.) Grimson also recites that “The laser scanning unit uses this unique mapping between image

plane points and 3D points in space to determine the 3D coordinates points *on the surface* of the patient's skin illuminated by the laser." (See Grimson, column 5, lines 17-21.) Grimson does not teach, disclose, or suggest a second acquisition means that measures *an unexposed portion* of the operation site with ultrasonic waves during surgery.

For the reasons discussed above, Applicants submit that Grimson fails to teach each and every element of the claims 1, 4, 6, 7, and 10. Furthermore, Grimson not only fails to disclose all of the limitations claimed, but also fails to disclose all of the limitations arranged or combined in the same way. Thus, claims 1-10 are patentable over this reference. Reconsideration and withdrawal of the rejection are respectfully requested.

Claim Rejections Under 35 U.S.C. § 103

The Examiner rejected claims 2, 3, 5, 8, 9, and 11 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Grimson. The rejections are respectfully traversed.

Claims 2, 3, 5, and 9 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Grimson as applied to claim 1. Claim 8 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Grimson as applied to claim 4. The Examiner asserts that Grimson teaches all the limitations of independent claim 1. Specifically regarding claims 2, 3, and 5, the Examiner admits that Grimson does not explicitly teach that the laser unit is mounted on a surgical probe. (See Office Action at pages 10, 11, and 13).

The Examiner contends that it would have been obvious to one of ordinary skill in the art at the time of the invention to expand the system method of Grimson et al. to place the scanning unit for the first acquisition in a surgical probe. One of ordinary skill in the art at the time of the invention would have been motivated to expand the system method of Grimson et al. to provide a surgical imaging method and system which generates real-time, adaptive, enhanced visualizations of the patient in the operating room (See Office Action at pages 10-11).

Applicant respectfully submits that Grimson fails to teach, suggest, or render obvious a "second position information representing a three-dimensional position of each of points in the **unexposed portion of the operation site**" as recited in claim 1. As presented above Grimson, does not teach every element and limitation of independent claim 1. Applicants submit that a dependent claim incorporates each of the claim elements of the independent

claim it properly depends from. Therefore, Applicants also respectfully request withdrawal of the §103 rejection and indicate the allowance of the dependent claims 2,3, 5, 8, and 9 by virtue of their respective dependencies from independent claim 1.

Independent claim 11 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Grimson. The Examiner contends that because the image data processor as taught by Grimson could be an IBM RS6000 or IBM PVS in conjunction with a Sun Sparc 10 (*See* Grimson, Column 5, lines 48-50), it is therefore to one having ordinary skill in the art at the time of the invention was made to recognize the image processor unit has an embedded program that causes the system disclosed by Grimson et al. to operate. (*See* Office Action, at pages 16-17).

Applicants respectfully submit, that even if the image processor unit, can be considered computing hardware with an embedded program, Grimson does not disclose, teach, or suggest all of the elements and limitations in amended independent claim 11. Independent claim 11 recites elements similar to independent claim 1. The remarks made above regarding independent claim 1 and the Grimson reference, similarly apply to claim 11. With respect to newly amended independent claim 11, Grimson fails to disclose, teach, or suggest A computer readable medium storing surgical operation supporting program that causes a computer to execute a process comprising “**measuring an unexposed portion of the operation site with ultrasonic waves generated by a probe during the surgery**” and that “**the unexposed portion of the operation site being below the surface of the operation site.**” Applicants respectfully submit that Grimson fails to teach each and every element of the newly amended independent claim 11, and therefore claim 11 is nonobvious in view of the cited reference.

Because the independent claims are believed patentable, it is not necessary to discuss patentable limitations of claims depending therefrom, the references, or the rejections. The lack of a discussion of patentable limitations of those dependent claims should not be construed to mean that there are not patentable limitations in those dependent claims.

All reasons for patentability of the independent and dependent claims have not necessarily been discussed herein. No implication or construction should be made therefore.

Applicants have no further remarks with regard to any references cited by the Examiner and made of record, whether or not acted upon by the Examiner in the action’s

rejections, even if specifically identified in the action or any other paper or written or verbal communication. No implication or construction should be drawn about any review of the same by Applicants or Applicants' attorney.

Based on the foregoing, it is submitted that the Applicants' claims 1-11 are patentable over the references of record. Issuance of a Notice of Allowance is solicited.

Applicant's attorney welcomes the opportunity to discuss the case with the Examiner in the event that there are any questions or comments regarding the response or the application. This is intended to be a complete response to the Examiner's Office Action mailed on May 12, 2009.

We hereby authorize the United States Patent and Trademark Office to charge any additional fees, which may be required or credit any overpayment, to Deposit Account 50-1662.

Respectfully submitted,

POLSINELLI SHUGHART PC

/Robert O. Enyard Jr./

Robert O. Enyard, Jr., Reg. No. 57,780
100 South Fourth Street, Suite 1100
St. Louis, Missouri 63102
Tel: (314) 889-8000
Fax: (314) 231-1776
Attorney for Applicants